

58. The apparatus of claim 48, where the anchoring members are substantially oval in cross-section.

59. The apparatus of claim 48, where the anchoring members have a top portion and the top portion is substantially flat.

REMARKS

Claims 1, 2, 7-11, 22 and 24-27 are pending. Claims 1, 2, 8-11 and 22 stand rejected for the reasons given in the outstanding Office Action. Claims 7 and 24-27 stand objected to as being dependent upon a rejected base claim. In response, claim 1 has been amended to correct a minor typographical error and claims 28-59 have been added. No new matter is added by these amendments. The amendment made by this Response and Amendment are identical to the amendments made by the Response and Amendment filed on September 18, 2000, which was not entered for the reasons given in the Advisory Action dated October 6, 2000. Entry of these amendments are hereby requested.

With respect to the Rejections under 35 U.S.C. §102, Paragraphs 4-5 of the Outstanding Office Action:

Claims 1, 2, 11 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent 5,681,347 to Cathcart et al., the Patent and Trademark Office stating that "Cathcart et al disclose a device 10 comprising a tubular element 13 comprising a hollow tubular lumen, a deployment means 17, and a plurality of resilient anchoring member 24 as claimed." The '347 Patent discloses a vena cava filter delivery system as follows (emphasis added):

A delivery system 10...comprises a proximal base 11 suited for positioning exteriorly of a patient and a distal portion 12 for insertion into a patient. The distal portion 12 includes an outer tubular member 12 proximally extending along an axis 14 from a distal end 15 of the system 10 to a handle 16 of the proximal base 11, **an inner member 17** co-axially underlying the outer member 13 and extending distally from the handle 16, and a metal tubular segment 20. The metal segment 20 has a substantially smooth inner bore.

Referring to Fig. 3, **a cup shaped portion 21** engages a proximal end 22 of a device 23, such as a vena cava filter having radially extending penetrating or hook

portions 24 disposed within the inner portion of the metal segment 20.... Displacement of the inner member 17 distally relative to the outer member 13 moves **the cup shaped portion 21** from the first position depicted in FIG. 3 through a second position depicted in FIG. 4 to a third position depicted in FIG. 5 in which the **cup shaped portion 21** distally extends beyond the distal end 15 and the filter 23 deploys in a patient's lumen. [col. 5, line 47 through col. 6. line 2]

Claim 1 in the present application, by contrast, contains the limitation that the apparatus for anchoring a tubular element comprises:

...deployment means positioned within the outer lumen and slidable with respect to the outer lumen, the deployment means comprising a hollow tubular inner lumen with a wall having an inner surface, where the inner lumen has a proximal end and a distal end, and **where the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end...**

As can be appreciated from these passages among others, and from the figures, the inner member 17 is not described as a "deployment means" in the '347 patent. In fact, the *structure* deployment means in the '347 patent necessarily includes the cup shaped portion 21 sealing the distal end of the inner member 17 to deploy the device 23 as disclosed in the '347 Patent. Otherwise, the deployment means disclosed in the '347 patent will not work. By contrast, the deployment means as claimed in claim 1 has a bore extending completely through the inner lumen from the proximal end to the distal end. Therefore, claim 1 as presently written is neither anticipated nor even suggested by the '347 patent, as the '347 patent does not disclose a deployment means with "a bore extending completely through the inner lumen from the proximal end to the distal end."

Additionally, claim 1 contains the limitation "...each anchoring member being **reversibly movable** by the deployment means between a first position and a second position..." (emphasis added). The 'anchoring member' (the filter 23) disclosed in the '347 patent does not appear to be 'reversibly movable by the deployment means (delivery system 10) between a first position and a second position.' Indeed, the disclosure in the '347 patent appears to be limited to non-reversible deployment of the filter 23 by the delivery system 10. For example:

...Thus, once the metal segment 20 and the stop 33 engage, the continued relative proximal displacement of the outer tubular member 13 relative to the filter 23 caused the deployment of the filter 23 from the distal end 15 with the cup shaped member 21 moving through the metal segment 20 to the position depicted in FIG.5. After deployment of the filter 23, the delivery system 10 is withdrawn by retracting the outer tubular member 13 either along the guidewire, if it remains so positioned, or merely along the path defined by the outer tubular member 13. [col. 7, lines 4-15]

If the Patent and Trademark Office continues to take the position that the '347 patent anticipates claim 1, the Patent and Trademark Office is requested to specifically identify the disclosure in the '347 patent that anticipates the limitation "...each anchoring member being reversibly movable by the deployment means between a first position and a second position..." present in claim 1.

For each of the reasons given above, claim 1 is believed to be patentable over the '347 Patent. Claims 2, 10-11 and 22 depend on claim 1. Therefore, withdrawal of the rejection under 35 U.S.C. §102(b) is hereby requested.

With respect to the Rejections under 35 U.S.C. §103, Paragraphs 6-9 of the Outstanding Office Action:

Claims 8-10 stand rejected under 35 U.S.C. §103(a) for the reasons given in paragraphs 3-5 of the outstanding Office Action. Each of these claims are dependent on claim 1. For the reasons given above, claim 1 is believed to be patentable. Therefore, these rejections under 35 U.S.C. §103 are now believed to be moot and withdrawal of these rejections is hereby requested.

With Respect to Claims 7 and 24-27, and New Claims 28-47:

Claims 7 and 24-27 stand objected to as being dependent upon a rejected base claim. In response new claims 28 through 47 have been added. Claim 28 is identical to claim 1 before this Response and Amendment except that the phrase "a plurality of resilient anchoring members attached to the distal end of the inner lumen" has been replaced with --a plurality of resilient anchoring members attached within the wall of the inner lumen--, reflecting the limitation of claim 24, and a typographical error, "an bore" has been corrected.

Claims 29 through 37 depend on claim 28.

Similarly, claim 38 is identical to claim 1 before this Response and Amendment except that the phrase “a plurality of resilient anchoring members attached to the distal end of the inner lumen” has been replaced with --a plurality of resilient anchoring members attached to the inner surface of the wall of the inner lumen--, reflecting the limitation of claim 25, and a typographical error, “an bore” has been corrected. Claims 39 through 47 depend on claim 38. Therefore, claims 28 through 47 are believed to be in condition for allowance.

With Respect to New Claims 48-59:

Additionally, claims 48-59 have been added. These claims are identical to pending claims 1, 2, 7-11, 22 and 24-27, except that the limitation in claim 1 “where the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end” has been removed in claim 48 and the word --fixedly-- has been added to the phrase “a plurality of resilient anchoring members **fixedly** attached to the distal end of the inner lumen and extending longitudinally beyond the distal end of the inner lumen...” Support for the word “fixedly” can be found, among other places at page 16, line 16 to page 17, line 4 as follows (emphasis added):

Typically, the anchoring members are first manufactured as separate structures rather than as a unitary structure with the other components of the apparatus 10, and then they are assembled together. The anchoring members may be attached to the deployment means by various methods known in the art, depending on what material the anchoring members and deployment means are comprised of. If the anchoring members are comprised of a pseudoelastic material, such as nickel titanium, the anchoring members may be attached to the deployment means by **welding or by soldering** with tin-silver or tin-gold, and using an aggressive flux. In addition, the anchoring members may be **press-fit, crimped, or swedged** to create attachment to the deployment means. In addition, attachment with an **epoxy** may also be used. Occasionally, for low stress applications, the pseudoelastic material may be **laser welded**, followed by a post-weld heat treatment to relieve stress at the joint. If the anchoring members are comprised of a spring steel material, the anchoring members may be attached to the deployment means by **welding or by soldering**.

As can be appreciated from the disclosure of the present invention, the anchoring

members in the present invention must be fixedly attached to the apparatus in order for the device to function as “[a]n apparatus for anchoring a tubular element within a passageway formed in a mammalian body,” while the anchoring members 24 referred to by the Patent and Trademark Office with respect to the '347 Patent, actually referred to as “radially extending penetrating or hook portions 24” in the '347 Patent, must NOT be fixedly attached to the corresponding structure for the device to function in the '347 Patent. Again referring to the '347 Patent disclosure:

...Thus, once the metal segment 20 and the stop 33 engage, the continued relative proximal displacement of the outer tubular member 13 relative to the filter 23 caused the deployment of the filter 23 from the distal end 15 with the cup shaped member 21 moving through the metal segment 20 to the position depicted in FIG.5. After deployment of the filter 23, the delivery system 10 is withdrawn by retracting the outer tubular member 13 either along the guidewire, if it remains so positioned, or merely along the path defined by the outer tubular member 13. [col. 7, lines 4-15]

Hence, it would not be possible to withdraw the delivery system if the radially extending penetrating or hook portions 24 were fixed attached to the delivery system.

For these reasons, claim 48 is believed to be patentable over the '347 Patent. Claims 49-59 depend on claim 48. Therefore, each of claims 48-59 are believed to be patentable over the '347 Patent.

CONCLUSION

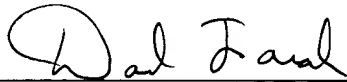
For the reasons given above, the Applicant believes that all pending claims, claims 1-2, 7-11, 22 and 24-59 are patentable and an allowance of these claims is earnestly solicited. If, however, there are any questions that can be addressed by telephone with the Applicant's representative, the Examiner is requested to contact the undersigned.

Please deduct all fees associated with this communication, including the fees for the added claims, from Deposit Account No. 19-2090.

Respectfully submitted,

SHELDON & MAK

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